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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------|-------------|----------------------|------------------------|------------------|
| 10/687,402 | 10/16/2003 | Jaya Sivaswami Tyagi | AP35478 066123.0125 | 8618 |
| 21003 | 7590 | 03/28/2006 | EXAMINER | |
| BAKER & BOTTS | | | FERNANDEZ, SUSAN EMILY | |
| 30 ROCKEFELLER PLAZA | | | ART UNIT | |
| NEW YORK, NY 10112 | | | PAPER NUMBER | |

1651

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|--|---------------------------------------|-------------------------------------|--|
| <p align="center">Advisory Action Before the Filing of an Appeal Brief</p> | Application No. 10/687,402 | Applicant(s) TYAGI ET AL. | |
| | Examiner Susan E. Fernandez | Art Unit 1651 | |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 March 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 03 March 2006. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☒ They raise the issue of new matter (see NOTE below);
 (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: 1-6.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
 13. ☐ Other: _____.

ATTACHMENT TO ADVISORY ACTION

The response filed March 3, 2006, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

The proposed amendment filed on March 3, 2006 will not be entered because the new language in the proposed amendment requires consultation of the specification to confirm support for the new language. Specifically, the claims previously did not require that DevR, DevS, Rv2027c, and their single domain derivatives are “recombinant.” Moreover, inclusion of this new language would require a new search. Additionally, the amendment presents additional claims without canceling a corresponding number of finally rejected claims. Therefore, denial of entry of the proposed amendment is proper at this after-final stage of prosecution.

All of applicant’s argument has been fully considered but is not persuasive of error. To the extent the applicant’s argument are applicable to the claims as pending, it does not demonstrate error for the reasons of record. With respect to the rejections under 35 U.S.C. 112, first paragraph, as stated in the final office action, the recitation “SDS-PAGE based high throughput assay” in claim 1 lacks support in the disclosure as filed. Instead, support is provided in the disclosure for the use of either SDS-PAGE or high throughput assays. Additionally, the recitation of “DevB” protein recited in claim 1 lacks support in the disclosure.

With respect to the argument that paragraphs [0001], [0059], and [0064] provide support for the limitation in claim 1 wherein the potency of the drug is inversely proportional to “the degree of phosphotransfer from phosphorylated DevS, and Rv2027 proteins to DevR,” it is respectfully pointed out that the requirement that drug potential is inversely proportional to “the degree of dephosphorylation of phosphorylated species of DevS and Rv2027c” does not state or suggest phosphotransfer to DevR. Figure 9 of the present invention also does not provide support for the claim language. Thus, the new matter rejections over the above limitation must be maintained.

With respect to the argument that paragraph [0117] provides support for the limitation in claim 1 wherein the drug potency is inversely proportional to “the degree of loss of phosphate-associated radioactivity from DevS/Rv2027c and DevR in a reaction containing DevS, DevR/Rv2027 and DevR,” it is respectfully pointed out that paragraph [0117] does not even state or suggest the presence of a drug, or that drug potency is inversely proportional to the net reduction in retention of radiolabel. Furthermore, Figure 15, purported support for the above claim language, does not expressly state the relation between drug potency and radioactivity. Thus, the new matter rejections over the above limitation must be maintained.

Finally, the §103 rejections over claims 1-6 as being unpatentable over Hoch et al. in view of Dasgupta et al. must be maintained. The applicant asserts that the mere identification of the homology of Rv2027c with DevS does not confirm the presence of similar characteristics such as phosphorylation properties. However, the suggestion that Rv2027c might play a role similar to that of DevS provides sufficient motivation for one

Art Unit: 1651

of ordinary skill in the art to recognize that the DevR-Rv2027c is the homolog of DevR-DevS. Additionally, Dasgupta et al. provides a DevS of 578 amino acid residues (Figure 5), a Rv2027 with at least 194 amino acid residues (Figure 3), and a DevR with at least 145 amino acid residues (Figure 5). Applicant does not provide evidence that there isn't a linear relationship between transcript size and protein length.

Additionally, applicant argues that the use of SDS-PAGE with multiple samples cannot be interpreted as "SDS-PAGE based high throughput assaying" due to the limitation of the number of samples that can be analyzed and time required to obtain quantitative results, citing column 2, lines 34-35 in the '045 patent. However, this section in the '045 patent pertains to another invention, and not to the invention of the '045 patent. Applicant has not provided any evidence that the use of SDS-PAGE as disclosed for the practice of the '045 invention cannot be considered "SDS-PAGE based high throughput assaying."

With respect to the argument that the '045 patent utilizes KinA and Spo0F proteins, and fails to disclose or suggest the application of the claimed experimental technique to the DevR-DevS/Rv2027c two-component systems, it is respectfully pointed out that Hoch et al. specifies that "it should be appreciated...that the disclosed assay systems can also be applied to other protein kinases and their substrates" (column 2, lines 65-67).

Further still, applicant asserts that in contrast to the assays described by the '045 patent, the claimed invention does not require assays in which the substrates are immobilized on a solid support. However, the claims do not recite that immobilization is not allowed. Also, the applicant asserts that the claimed invention is an improvement

Art Unit: 1651

over the prior art in that the use of a coupled assay in a filter –based format without the need to separate the kinase from the substrate is facilitated. However, the claims do not recite that separation of the kinase from the substrate is not permitted.

In conclusion, the rejections of record must therefore be maintained.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sef

Susan E. Fernandez
Assistant Examiner
Art Unit 1651



FRANCISCO PRATS
PRIMARY EXAMINER